U.S. Measurement System

NIST National Institute of Standards and Technology

Imaging as a Biomarker: Standards for Change Measurements in Therapy

Breakout Area 1: X-Ray & X-Ray CT:
What can be measured over time?

Day 2: Summary
"The Detailed Measurement Science & Standards Needs – The What by When and by Whom"
Near, Mid-Term Issues Only

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Breakout Area 1: X-Ray & X-Ray CT: What can be measured over time?

Measurement Need #1 for Near-Term 1-3 Years

1. *Technology at Issue:* Quantitative CT
2. *Submitter(s):* Charles Peterfy, Geoffrey McLennan, Thomas Fuerst, Robert Ford, Sean Zhou & Company
3. *Technological Innovation at Stake:* Characterization of structural change of pathology by quantitative analysis of CT images
4. *Economic Significance of Innovation*: 50 million+ individuals with lung nodules, 190,000 lung cancers diagnosed per year. $14 billion per year spent on treatment of osteoporotic fractures.

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5. *Technical Barrier to the Innovation*:

- lack of understanding of the errors sources in CT which affect quantification,
- lack of performance standards in CT or standard means to assess performance,
- uncertainty of minimally clinically significant change thresholds in relation to scanner variability,
- lack of information about tumor biology
- lack of a standard (phantom) and scanning protocols to assess scanner performance

6. *Stage of Innovation Where Barrier Appears*:

- R&D through End user

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7. Measurement-Problem Part of Technical Barrier:

- Need to have measurement and understanding of voxel characteristics between scanners
- lack of understanding of the errors sources in CT which affect quantification,
- lack of performance standards in CT or standard means to assess performance,
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- lack of information about tumor biology
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Measurement Need #1 for Near-Term 1-3 Years (cont'd)

8. Potential Solutions to Measurement Problem:

- Create a standard image database with "truth" data for investigating clinical significance thresholds and image processing methods (like LIDC, IDRI, RIDER, etc.). For example, for lung nodules, one can measure size (volume or area), function (perfusion), or structure (tissue characterization).
- For this need standardization of the basic unit of measurement across scanners – this is the voxel for CT. The variance in this measure needs to be understood with an intensity and spatial/geometrical phantom as well as a "biological tissue phantom" (suitable for the task),
- Develop appropriate phantom for scanner performance evaluation;

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Measurement Need #1 for Near-Term 1-3 Years (cont'd)

9. *Potential Providers of Solutions:*
   Academia, NIH, NIST, NEMA, AAPM, phantom vendors, CT vendors

10. *What is the role for Government, if Any?:*
    NIH and NIST facilitating, and supporting research where needed. NIST providing guidance on phantom development based on common metrology methods.

11. *If There is a Government Role, Why Industry Says It Can't/Won't Pay for That Part of Solution:* Clinical trial market too small; financial return on investment uncertain; requires cross-industry collaboration; expensive